

CLIA NON-WAIVED LABORATORY TESTS

Personnel Competency Assessment

Employee Name: _____ Title _____ Date _____ Next Assessment Due: _____

New Employee: Yes ☐ No ☐ Competency Assessment: Initial ☐ Semi-Annual ☐ Annual ☐

Guidelines Competency based on direct observations & record review	Gram Stain			KOH			Wet Prep																	
	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA
1. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing																								
2. Monitor the recording and report of test results																								
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records																								
4. Direct observation of performance of instrument maintenance and function checks																								
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples																								
6. Assessment of problem solving skills																								

Areas of employee competency that requires improvement _____

Training plan and date of completion _____

Competency Assessor _____
Print Name
Signature
Date _____

Laboratory Manager _____
Print Name
Signature
Date _____

Laboratory Director Review _____
Print Name
Signature
Date _____

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Guidelines Competency based on direct observations & record review	Hemocue Glucose			Hemocue Hemoglobin			Hemocult			Rapid Strep			Urine Hcg			Rapid HIV INSTI			Rapid HIV Determine			Rapid Syphilis Health Check		
	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA
7. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing																								
8. Monitor the recording and report of test results																								
9. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records																								
10. Direct observation of performance of instrument maintenance and function checks																								
11. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples																								
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Guidelines Competency based on direct observations & record review	Chem Strips (UA)			Multistix (UA)			Lead			HbA1c			Rapid Influenza A & B			Drug of Abuse Card Test (Urine)			Rapid HCV Ab Test					
	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA	Yes	No	NA
13. Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing																								
14. Monitor the recording and report of test results																								
15. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records																								
16. Direct observation of performance of instrument maintenance and function checks																								
17. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples																								
18. Assessment of problem solving skills																								

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Print Name
Signature
Date _____

Laboratory Manager _____
Print Name
Signature
Date _____

Laboratory Director Review _____
Print Name
Signature
Date _____

**Competency Testing for Laboratory
Personnel Procedures**

Procedure/Clinical Services

Agency Name

Initial: Date

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REFERENCES:

State Operations Manual, Appendix C – Survey Procedures and Interpretive

Guidelines for Laboratories and Laboratory Services, Table of Contents, (Rev. 166,
02-02-2017)

POLICY:

Agency Name are committed to complete Competency Testing in accordance with CLIA guidelines. Competency Testing is defined as the application of the knowledge, skills and behaviors for performance. Competency Testing assessment confirms that employees are doing the testing correctly.

PROCEDURES:

- A.** The technical consultant/supervisor is responsible for assessing the competency of the testing personnel.
 - 1. The technical consultant/supervisor is responsible for assessing the competency of the testing personnel.
 - 2. The Competency Testing will be evaluated using the six competency criteria (see attached check off sheet).
- B.** Competency Testing will be completed by all employees that participate in performing any type of lab test.
 - 1. Competency Testing for personnel will include competency testing of all lab processes that employee performs.
 - 2. Competency Testing must be performed on all waived and non-waived.
- C.** Evaluating and documenting competency of personnel responsible for testing is required at least semi-annually during the first year the individual tests patient specimens. Thereafter, Competency Testing assessment must be performed at least annually.

Name**Laboratory Director**